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**From:** Lavoie, Emma [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=86AC7844F12646C095E4E9093A941623-LAVOIE, EMMA]  
**Sent:** 12/18/2017 8:03:13 PM  
**To:** Orme-Zavaleta, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c5a111dc377411595e5b24b5d96146b-Orme-Zavaleta, Jennifer]; Thayer, Kris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ce4ae3f107749c6815f243260df98c3-Thayer, Kri]; Bateson, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29bfdde020bf4e93b431b9a72d9d230f-Bateson, Thomas]; Bahadori, Tina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7da7967dcafb4c5bbc39c666fee31ec3-Bahadori, Tina]  
**Subject:** RE: Prep for IRIS meeting

All,

Some definitions you may want at hand for discussion today or for tomorrow.

Risk eval rule is [here](#).

SR definition from preamble is:

11. Systematic Review. EPA requested comment on the need for regulatory text prescribing a specific systematic review approach for hazard identification, including the appropriateness of elements that might be included or concerns about codifying an approach. Commenters both supported and opposed the inclusion of systematic review in the rule text. Those opposing the codification of systematic review argued that EPA should retain flexibility and the ability to change the process as improved methods for systematic review are developed. Some commenters did encourage a description of the intended approach in the preamble, but suggested that EPA reserve the specific process for guidance. Those in support of codifying a description of systematic review in the rule text stated that inclusion would increase transparency and would provide the public with an indication of how the statutory requirement of weight of the scientific evidence, requirements of sections 6 and 26, and an integral component of systematic review, will be applied. EPA intends to use the systematic review approach, described in the proposed rule, but is not codifying a definition in the regulatory text. To be clear, although EPA asked for comment on the need for regulatory text for systematic review on hazard identification specifically, EPA will not limit the use of this approach solely to the hazard assessment, but will use it throughout the risk evaluation process. The inclusion of a description of systematic 33 review in the preamble is the most appropriate approach in light of public comment and the requirements of the statute. First, systematic review is not required under the statute, only a weight of the scientific evidence analysis. The definition the Agency is adopting for “weight of the scientific evidence” uses the phrase “systematic review,” which addresses to some extent the commenters who favored including the concept in this regulation. EPA sees weight of the scientific evidence approach as an interrelated part of systematic review, and further believes that integrating systematic review into the TSCA risk evaluations is critical to meet the statutory requirements of TSCA. Although, as EPA discusses elsewhere in this preamble, there are universal components of systematic review that EPA intends to apply in conducting risk evaluations, this is one area where EPA concluded it would be premature to codify specific methods and criteria that may change as the Agency gains more experience conducting TSCA risk evaluations. As requested by commenters, EPA does believe the addition of discussion of the systematic review approach the Agency intends on utilizing is necessary for transparency, and so provides the description herein. Section 26(l) also requires EPA to develop and revise Agency guidance. The Agency intends to provide further details on systematic review and weight of scientific evidence approaches under TSCA in future guidance documents. As defined by the Institute of Medicine (Ref. 11) systematic review “is a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. The goal of systematic review methods is to ensure that the review is complete, unbiased, reproducible, and transparent” (Ref. 11). The principles of systematic review have been well developed in the context of 34 evidence-based medicine (e.g., evaluating efficacy of medical interventions tested in multiple clinical trials) (Ref. 12) and are being adapted for use across a more diverse array of systematic review questions, through the use of a variety of computational tools. For instance, the National Academies’ National Research

Council (NRC) has encouraged EPA to move towards systematic review processes to enhance the transparency of scientific literature review that support chemical-specific risk assessments to inform regulatory decision making (Ref. 13). Key elements of systematic review include: - A clearly stated set of objectives (defining the question); - Developing a protocol which describes the specific criteria and approaches that will be used throughout the process; - Applying the search strategy criteria in a literature search; - Selecting the relevant papers using predefined criteria; - Assessing the quality of the studies using predefined criteria; - Analyzing and synthesizing the data using the predefined methodology; - Interpreting the results and presenting a summary of findings (Ref. 14)

And taken from the draft TSCA SR approach document, other key definitions:

## 1 SCIENTIFIC STANDARDS FOR TSCA RISK EVALUATIONS

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TSCA requires that, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, EPA must use certain scientific standards and make those decisions consistent with the best available science and based on the weight of the scientific evidence [15 U.S.C. 2625(h) and (i)]. In addition, TSCA section 6(b)(4) establishes specific substantive requirements for EPA-conducted risk evaluations [15 U.S.C 2605 (b)(4)].

### 1.1 Best Available Science

EPA will prepare TSCA risk evaluations using the best available science as described in TSCA [15 U.S.C. 2625(h)] and the final rule establishing the procedures for chemical risk evaluation (40 CFR Part 702.33).

In determining that best available science is an integral component of section 6 risk evaluations, EPA defined, by rulemaking, best available science as “*science that is reliable and unbiased. Use of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).*”

As defined in 40 CFR Part 702.33, implementing the best available science also means “*...to consider, as applicable:*

- *The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;*
- *The extent to which the information is relevant for the Administrator’s use in making a decision about a chemical substance or mixture;*
- *The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;*
- *The extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and*
- *The extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models.”*

### 1.2 .Weight of the Scientific Evidence

TSCA risk evaluations are required to rely on the weight of the scientific evidence [15 U.S.C. 2625 (i)]. In accordance with the final rule (40 CFR Part 702.33), the weight of the scientific evidence is defined as “*a systematic review method, applied in a fit-for-purpose manner, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence,*

*including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance."*

### 1.3 Data Quality

EPA will implement a data quality system that ensures that the TSCA risk evaluation uses quality data intended for risk assessment purposes consistent with the requirements of TSCA [15 U.S.C. 2625(h) and (i); 2605 (b)(4)]. EPA will use the approaches set forth in the rule at 40 CFR Part 702 and the accompanying preamble to prepare the various sections of TSCA risk evaluations. Moreover, EPA will disclose and make publicly available raw data used to support the draft risk evaluation, if not previously reported in the literature, with the exception of confidential business information (CBI) that may be considered in the preparation of the risk evaluation.

-Emma

Tel: 202 564 7091

-----Original Appointment-----

**From:** Orme-Zavaleta, Jennifer

**Sent:** Monday, December 18, 2017 2:00 PM

**To:** Orme-Zavaleta, Jennifer; Lavoie, Emma; Thayer, Kris; Bateson, Thomas; Bahadori, Tina

**Subject:** FW: Prep for IRIS meeting

**When:** Monday, December 18, 2017 4:00 PM-4:30 PM (UTC-05:00) Eastern Time (US & Canada).

**Where:** 41209 RRB

-----Original Appointment-----

**From:** Orme-Zavaleta, Jennifer

**Sent:** Monday, December 18, 2017 10:42 AM

**To:** Orme-Zavaleta, Jennifer; Bahadori, Tina

**Subject:** Prep for IRIS meeting

**When:** Monday, December 18, 2017 4:00 PM-4:30 PM (UTC-05:00) Eastern Time (US & Canada).

**Where:** 41209 RRB

Prep for meeting with Nancy Beck tomorrow